

Patent Application No.: 09/919,275

### **REMARKS**

The Office Action of November 3, 2004 has been carefully considered. Reconsideration of this application, as amended, is respectfully requested.

As noted at pages 2 and 3 of the instant application, the system is believed to be distinguishable from other medical diagnostic systems that simply seek a set of symptoms and input the symptoms to an artificial-intelligence engine to create a definitive diagnosis. Wilk and Bodick do not address the essential challenge of the visual diagnostic process; perception and recognition of visual variants. Tolerating the ambiguity of paradoxical visual and non-visual clues and the uncertainty inherent to medicine and the biologic diagnosis and recognition is an essential feature of this application.

Bodick primarily addresses building a knowledge database and does not address how a physician would be able to consider hundreds of diagnostic images in a timely manner within the context of the patient examination. The inclusionary/exclusionary matching process suggested by Bodick simply links knowledge contained within a database to the subject (patient). With thousands of images to be considered within each sub-specialty field, Bodick fails to address how diagnostic information is matched precisely. Bodick's invention assumes that medical decision-making contains definitive branch or algorithmic logic requiring one simple match. Medical decision making is inherently "gray", system design must model the constant of variation and ambiguity and the need to consider multiple medical findings in parallel and dynamically at the time of diagnosis. Hence, the present invention uses categories or constellations of patient findings, or sample characteristics, to provide a combination of textual and graphic/image information to the user, so that the user may test or review a plurality of possible diagnoses without being "lead" to one diagnosis over another. In other words, the present system provides a source of knowledge (medical or other), in multiple forms, that allow users to test diagnostic hypotheses against an image database using patient findings or sample characteristics so the closest image matched are viewable in a condensed information space.

The system (and method) builds upon an innate human ability to match patterns. This is the basis for any pictorial handbook or guide, such as atlases in medicine. Moreover, all visual identification problems benefit from user experience and

Patent Application No.: 09/919,275

knowledge. When prior visual knowledge is limited, picture or image "centered" reference materials can assist the inexperienced. However, paper-based, pictorial references have a linear structure and do not allow for user-defined groupings and matching of pictures. Software based image systems offer the possibility of combinatorial searching as well as user-defined comparison of possibilities. The visual diagnostic embodiment of the present system/method, assembles textual and visual knowledge, thereby creating the ability to "presort" and display images so that a user can more effectively engage in pattern matching. These unique functional, organizational and graphical display capabilities are useful within any professional area where an individual has to make a visual "diagnosis" or identification, or recognize a visual feature.

Displaying images of suggested relevant diagnoses (or identifications in the non-medical embodiments) is a central objective and focus of the present invention, including its knowledgebase and applications thereof. Diagnoses may be displayed textually and/or visually. As described, the visual display of diagnostic information is through links to images associated with the knowledge base. In some embodiments, diagnoses have a summarizing picture icon, usually a close-up view of the most visually defining characteristic, abstract icons or designated characteristic thumbnail images for situations where many diagnoses are arrayed in a menu.

Turning now, to the office action, the Examiner has acknowledged the grouping of claims 1-4 with the election by Applicants, hence claims 1-24 and 28 are being examined, claims 25-27 and 29-30 having been previously withdrawn. Claims 1 – 24 and 28 were rejected under 35 USC §103(a) as being unpatentable over US 5,437,278 to Wilk (Wilk) in view of US 4,945,476 to Bodick et al. (Bodick).

Applicants appreciate the Examiner's detailed indication of those portions of the cited references relied upon for the rejection and Applicants have, in response, sought to provide a similar level of information. The disclosures of the cited art and the distinctions between claims 1 – 24 and 28 may be briefly summarized as follows:

Wilk discloses a medical diagnostic system that is described as having a device 20 for monitoring and measuring a biological or physiological parameter, transmitting the parameters to a computer 24, and ultimately communicating a medical diagnosis as determined by the computer. At col. 5, lines 30-31, Wilk suggests a video camera for obtaining an image of a portion of a patient's skin. And, as noted by the Examiner,

Patent Application No.: 09/919,275

Wilk suggests use of the system for dermatological diagnosis wherein images of skin conditions are stored (col. 2, lines 46-56 and col. 6, lines 17-21). However, Wilk is directed to an automated medical diagnostic system (e.g., col. 3, lines 51-52), whereas the present invention recognizes the inherent problems with such systems and is intended, as recited in the preamble, to aid in the diagnostic process – not as a substitute for a medical professional's diagnosis, but to visually assist them with the diagnosis. Applicants respectfully contend that Wilk's automated diagnostic system teaches away from the visual aid intended by the present invention. This distinction is further evident in that the systems and methods recited in the independent claims do not require the uploading or transmission of image data for computer analysis, but relies on the user's visual comparison, of previously stored images (image database) related to possible diagnoses, to that which is observed by the user.

While Wilk does disclose the storage of images, it does not disclose the storage of images in an image database, separate from a knowledgebase, nor the cross-referencing of the image database with the knowledgebase for purposes of assisting in the diagnostic process as recited in the rejected independent claims (e.g., claims 1, 3, 5 and 28). Applicants review of Wilk, both in the locations referenced and in its entirety, did not identify any reference to a database, or separate image and knowledge databases. Rather, what was found was reference to bulk storage and memory (e.g., 28 in Fig. 1), which do not teach the recited databases.

Similarly, Applicants review of Wilk, particularly at columns 4 and 7, fails to identify a user interface to "solicit ... a plurality of descriptive characteristics of a sample requiring diagnoses" and use of such characteristics to automatically identify a subset of diagnoses as recited in amended claim 1. Although Wilk does describe a keyboard used for entry of information identifying the patient (col. 4, lines 50-51), it would be absurd to describe this as a disclosure of soliciting characteristics, as the term has been used in the rejected claims, as to do so would thereby suggest that a diagnosis may be determined from information identifying the patient. Wilk clearly teaches that it is devices 20 (thermometer, blood pressure gauge, etc as described at col. 4, lines 32-39) that provide the information upon which a diagnosis is determined.

Moreover, as the Examiner has acknowledged, Wilk also fails to disclose identifying a subset of diagnoses and use of the subset to reorganize the information space of

Patent Application No.: 09/919,275

the image database, as required by the rejected claims. Also, Wilk clearly teaches away from the automatic determination of a subset of diagnoses as it discloses a medical diagnostic system – where there would be no need or usefulness in displaying images (reorganized or not) for review. In light of Wilk's teachings, it is apparent that Wilk teaches away from a system (e.g., claims 1, 5, 28) or method (e.g., claim 3) designed to aid in visual diagnoses.

Bodick, cited by Applicants, teaches the creation of a knowledge base containing both pictorial images and textual information therein (col. 2, lines 39-40), along with a system to use such information in medical diagnosis. The system is further described as being dynamic; to permit the addition of newly discovered characteristics observed in patients and deletion of characteristics having little diagnostic importance. As Bodick points out, the disclosed knowledge base is distinct from a classic database (col. 3, lines 12-16).

Although Bodick does describe alternative methods of accessing the knowledge base (by cases having specific features or by cases in which a particular disease was diagnosed; col. 5, lines 42-48), Applicants respectfully submit that such a teaching does not give rise to the recited limitations of "automatically identify[ing], from a plurality of possible diagnoses, a subset including a plurality of diagnoses that are consistent with the characteristics." As to the recited limitation of "automatically reorganizing an information space of said image database for concurrent presentation of a plurality of images for user review," Applicants respectfully submit that no such teaching is found in Bodick, and that Bodick, in fact, teaches away from such a limitation. For example, at col. 2, lines 59-61, where a comparison is described between "one patient or sample" and a "previous patient or sample" there is a strong implication that only a single representation is being displayed. Similarly, col. 6, lines 19-22 of Bodick clearly indicate that information from a single record is displayed – not concurrent display of a plurality of images reflecting a subset of diagnoses.

As to the basis for the alleged combination, the Examiner urges that it would have been obvious to modify Wilk to incorporate searching and image display as taught by Bodick. Applicants respectfully challenge this basis, as there is no indication cited by the Examiner why one would have been motivated to modify the automated diagnostic system taught by Wilk to make it an "unautomated" system that is used for

Patent Application No.: 09/919,275

searching of case data – particularly when one further appreciates that Wilk states that the system will make diagnoses by computer (col. 3, lines 58-60), and that Wilk was filed and granted after Bodick was issued. In other words, no motivation is found in Bodick to suggest making an automated diagnostic system a manual system. Nor is it clear how one of ordinary skill in the art would be motivated by any suggestion of benefit to physicians to modify a system designed to “replace” physicians. Accordingly, Applicants respectfully urge that the various statements of Bodick and Wilk would suggest that the teachings were not combinable. In light of such teachings, Applicants respectfully urge that the combination of Wilk in view of Bodick is not supported by the references themselves, and was motivated solely by the limitations of the rejected claims themselves. In the event the rejection is maintained, Applicants respectfully request that the basis for the rejection set forth compelling motivation to counter the clear teaching away from the proposed modification/combination.

Considering, *in arguendo*, the combination of Wilk in view of Bodick, at most such a combination teaches the use of a common collection of data or knowledge, for an automated medical diagnostic system. The modifications suggested by Bodick (with arguments to the contrary presented above) would at most suggest that data of the Wilk system may be searched and text and/or an image from a case displayed to a user of the system as suggested by Bodick. Such a combination or modification does not, however, give rise to the separate image and knowledge databases recited in rejected claim 1, for example, as neither of the patents teach or suggest such a limitation.

The arguable combination of Wilk in view of Bodick also fails to teach or suggest a user interface to solicit a plurality of descriptive characteristics of a sample requiring diagnosis as recited in claim 1. And, as noted above, neither Wilk nor Bodick teach the automated identification of a subset having a plurality of diagnoses, in response characteristics. Rather, the arguable combination teaches, at most, the manual searching of case records, and as suggested by Bodick, the display of an image and text associated with the case record. Applicants respectfully submit that as a result of neither reference teaching the automatic reordering of an information space and concurrent presentation of a plurality of images for user review, as recited in independent claims 1 and 3, the claims are patentably distinguishable over the arguable combination.

Patent Application No.: 09/919,275

With regard to claims 2 and 4, Applicants reiterate the arguments set forth above relative to claims 1 and 3, and respectfully urge that the Examiner has mistakenly characterized the search capability characterized by Bodick as providing the recited ability to reorganize the information space in response to a user's modification of a descriptive characteristic. Such a feature is depicted in Figures 7 and 8 and described at page 24 of the as-filed application – where a user's selection of a descriptive characteristic results in the alteration of the images displayed. As no such teaching is found or illustrated in Bodick, Applicants respectfully urge that claims 2 and 4 are also patentably distinguishable over the arguable combination of Wilk in view of Bodick.

With regard to claim 5, Applicants again incorporate the various arguments set forth above with respect to claims 1 and 3. In particular, Applicants respectfully maintain that Wilk discloses an automated medical diagnostic system, whereas claim 5 recognizes the inherent problems with such systems and is intended, as recited in the preamble, to reduce diagnostic uncertainty – not as a substitute for a medical professional's diagnosis. Applicants respectfully contend that Wilk's automated diagnostic system teaches away from the visual aid system characterized by claim 5. While Wilk does disclose the storage of images, it does not disclose the recited user interface, the storage of images in an image database, separate from a cross-referenced knowledgebase, let alone the acknowledged failure to disclose or suggest the automatic reorganization of an information space and concurrent presentation of images for user review. As noted above in the summary from pages 2 and 3 of the specification, Applicants believe this to be an important aspect of the claimed invention – the ability to provide a visual aid to a diagnosis, while not dictating or determining a diagnosis (as taught by Wilk). Both Wilk and Bodick fail to address a solution for diagnosing when there are thousands of variations and images that are at the core of medical diagnosis and the biologic world.

Bodick teaches the creation of a knowledge base containing both pictorial images and textual information therein (col. 2, lines 39-40), along with a system to use such information in medical diagnosis. Like Wilk, however, Bodick also fails to teach or suggest the automatic identification of a subset including a plurality of diagnoses, and then using the subset, automatically reorganizing the information space to provide for its presentation to the user – using concurrent presentation of multiple images for review. As these limitations are not found in either Wilk or Bodick, even if the

Patent Application No.: 09/919,275

arguable combination is considered, the rejected claim cannot be rendered obvious. Absent a teaching relative to the recited identification of a plurality of diagnoses, and the automated reorganization of the information space in an image database for concurrent presentation of images (specifically recited in claim 5), *prima facie* obviousness has not been established. Accordingly claim 5, and all claims dependent therefrom, is respectfully urged to be patentably distinguishable over the arguable combination of Wilk in view of Bodick.

With respect to amended claim 24, Applicants urge that in addition to being allowable for the reasons as set forth in traversing the rejection of claim 5, claim 24 has been amended to recite characteristics that Applicants believe are not found in the references currently relied upon for the rejection. Support for these characteristics is found at page 26 of the Specification. Accordingly, claim 24 is believed to be patentably distinguishable over Wilk and Bodick as well.

Turning to the rejection of claims 6 – 11, the Examiner has further urged that Bodick discloses a diagnostic image stack, as recited in the rejected claims, by its disclosure of a diagnostic tree in Fig. 26. Applicants respectfully urge that Bodick is clear as to the contents of Figure 26, and that lacking specific teaching of the various "nodes" in the figure, there is no teaching of the display of an image stack as used herein. The Examiner is referred to Figures 8 and 12-15 of the instant application, and the associated description at pages 24 – 25 of the Specification. Moreover, as noted by the Examiner, Bodick also fails to disclose the alteration of the image stack in accordance with disease progression (claim 8). Accordingly, Applicants respectfully submit that claims 6 – 11 are patentably distinguishable over the arguable combination of Wilk in view of Bodick, for the reasons set forth with respect to claim 5 and as more specifically set forth herein.

With regard to claim 12, in addition to being dependent from presumably allowable claim 5, claim 12 further recites using characteristics of diagnoses, solicited via the user interface, to perform pattern recognition and identify diagnoses with matching characteristics. On the other hand, Wilk teaches the comparison of digitized data from monitoring/measuring device 20 for purposes of deriving a diagnosis of the patient's condition. Thus, Wilk cannot teach what has been alleged; as to do so would require a user-interface and characteristics that are not taught or suggested by Wilk. Thus, Applicants urge that in addition to being dependent from allowable claim

Patent Application No.: 09/919,275

5, claim 12 is itself patentably distinguishable over the arguable combination of Wilk in view of Bodick.

With regard to claims 13-14 and 15, Applicants respectfully maintain that these claims are patentably distinguishable over the arguable combination for the reasons set forth above relative to claim 5. Moreover, while acknowledging that Wilk suggests use of the medical diagnostic system for dermatological diagnosis, there is no suggestion that such diseases must be of a type having visual findings visible to an unaided human eye or mechanical examination. In fact, the diagnostic input employed by the Wilk system is from the described devices, or possibly the video camera. However, there is no recitation or suggestion that the camera creates or the system relies upon findings visible to the human eye. Nor is there any suggestion of a mechanical examination means as set forth in claim 15. Hence, claims 13 – 15 are respectfully urged to be patentably distinguishable over the arguable combination of Wilk in view of Bodick.

With regard to claims 16-18 and 20-21, Applicants acknowledge the Examiner's Official Notice as to use of icons. However, even if use of icons was known at the time of the invention, their use in the manner recited in the rejected claims was not known, or obvious. Moreover, the Official Notice would appear to be in conjunction with Wilk and Bodick, yet the Examiner has not indicated where the motivation for making use of icons is taught or suggested. In fact, as has been Applicants' position in this response, Wilk needs no such icons as it is not a diagnostic aid, but a medical diagnostic system. Similarly, Bodick fails to suggest such use as Bodick does not appear to teach or suggest the particular manner in which the rejected claims use such icons (e.g., symptoms represented as icons; icon indicates distribution of lesions on body; shape of medication, color). Absent some teaching or suggestion of the recited limitations, at best the Official Notice is an attempt at a hindsight reconstruction of the claim elements using the instant application as the recipe. Applicants object to this use of Official Notice, and request that in the event the rejection is maintained the Examiner set forth document(s) teaching all of the recited limitations, and indicate the motivation for such a combination. Absent such information, Applicants respectfully contend that claims 16-18 and 20-21 are patentably distinguishable over the arguable combination and are in condition for allowance.



Patent Application No.: 09/919,275

Considering claims 19 and 22-23, each of these claims includes limitations relative to alternative uses of the system of claim 5. However, the rejection fails to establish where the recited limitations are taught or suggested by either Wilk or Bodick. For example, the identification of medications, as set forth in claim 19, is not taught or suggested as acknowledged by the Examiner. Nonetheless, it is urged that Bodick's suggestion of the use of image data is somehow suggestive of such a limitation. Absent a teaching or suggestion of the claimed limitation, obviousness cannot be established. Accordingly, Applicants maintain that the Examiner has failed to establish *prima facie* obviousness to which a response can or must be supplied. In the event that the rejection of claims 19 and 22-23 is maintained, Applicants request that the Examiner indicate where all of the limitations of the rejected claims are set forth in the references relied upon, and that Applicants be permitted an opportunity to amend and/or respond thereto in a non-final action.

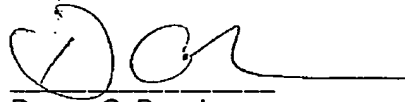
Relative to claim 28, Applicants arguments in the immediately preceding paragraph are further applicable to the rejection of this independent claim. In setting forth the rejection, the Examiner has failed to establish where each of the recited limitations is taught or suggested by the references relied upon – either alone or in combination. In particular, the Examiner acknowledges that none of the references of record is described as providing assistance in investigating a cause of death, nor are particular characteristics as to a manner of death, wound type, modality, etc. taught or suggested either by Wilk or Bodick. However, as in the rejection of claims 19 and 22-23, the Examiner nonetheless asserts that Bodick teaches the importance of using images and text “in any area where the appearance of an object under study/examination is of critical importance.” Notably, in contrast to the rejection of the other independent claims, the Examiner now fails to recite where such a suggestion is found in Bodick. Moreover, even if Bodick might be extended in the manner desired by the Examiner, such an extension does not give rise to a basis for the rejection – particularly when the rejected claim recites specific limitations not found in the references. Again, Applicants respectfully urge that claim 28 is presently allowable and that *prima facie* obviousness has not been established so as to require or permit a response. In the event that the rejection is maintained relative to claim 28, Applicants request that the Examiner specifically set forth that portion of the references relied upon for the teaching of all limitations, and that they be permitted further opportunity to amend and/or respond in a non-final action.

Patent Application No.: 09/919,275

In view of the foregoing remarks and amendments, reconsideration of this application and allowance thereof are earnestly solicited. In the event that additional fees are required as a result of this response, including any fees for extensions of time, such fees should be charged to USPTO Deposit Account No. 50-2737 for Basch & Nickerson LLP.

In the event the Examiner considers personal contact advantageous to the timely disposition of this case, the Examiner is hereby authorized to call Applicant's attorney, Duane C. Basch, at Telephone Number (585) 899-3970, Penfield, New York.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'DCB', followed by a horizontal line.

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